



We are looking for a **QA Specialist** to join our team!

Location: Tzur Yigal

Bioprotect Ltd developed a proprietary technology platform for biodegradable balloon. The technology suits a wide range of clinical applications including spacing for radiation oncology protection, aesthetics and general surgery. The company's first application in the commercialization stage is the BioProtect Balloon Implant™ System acting as a spacer for the protection of healthy tissue in patients receiving radiotherapy for prostate cancer.

General description: The candidate prime responsibility is to maintain BioProtect quality management system and support day-to-day activities according to the company quality manual and quality management system procedures, to ensure compliance with applicable quality and regulatory requirements, promote awareness and continuously improve effectiveness.

Roles & Responsibilities:

- Maintenance and update of company Quality Policy, Quality Manual and related procedures and forms
- Handling, control and maintenance of employees training and qualification
- Handling, control and maintenance of suppliers evaluation and approval process
- Participate and take an active part in MRB, CAPA, complaints and ECO meetings
- Overall control of documents and quality records
- Supporting internal and external audits
- Initiation, performance and documentation of corrective and preventative actions verification of their effectiveness
- Supporting MRB, ECO and customer complaints handling activities as required
- Supporting quality issues investigations
- Supporting QMS continuous maintenance and improvement
- Supporting routine equipment calibration and maintenance activities
- Working in close collaboration with R&D, Engineering, Operations, Regulatory, Clinical, Manufacturing and Marketing departments

Requirements:

- Relevant degree (e.g., science / technical discipline)
- At least 2 years related experience in a similar role, in a medical device company
- Experience and knowledge with standards and regulations (MDR 2017/745, ISO 13485, FDA QSR, ISO 14791 etc.)
- Ability to work under pressure to meet schedules and deadlines within quality and regulatory standards
- Strong verbal and written communication skills
- Strong problem-solving skills
- Excellent English language skills (verbal and writing)
- Experience with Class III implantable medical devices – an advantage
- Experience with working in controlled environment (clean room) – an advantage
- Project management experience – an advantage

Cvs to Marianna: marianna@bioprotect.com